K060559
p. 1 of 3

ZOLL Medical Corporation

Worldwide Headquarters
269 Mill Road
Chelmsford, Massachusetts 01824-4105
U.S.A.

978 421-9655
978 421-0025 Main Fax

ZOLL

510(k) Summary:

Submitter's Name and Address:

AUG 17 2006

ZOLL Medical Corporation
Worldwide Headquarters
269 Mill Road
Chelmsford, MA 01824-4105
(978) 421-9655

Contact Person:

Sean Reynolds
(978) 421-9655, Ext. 9386

Date Summary Prepared:

February 24, 2006

Device:

ZOLL R Series

Classification:

Defibrillator, Low-energy – DC: Class II (21 CFR 870.5300)

Automated External Defibrillator: Class III (21 CFR 870.5310)

Cardiopulmonary Resuscitation Aid: Class III (21 CFR 870.5200)

Cardiac Monitors (including Cardiotachometers and Rate Alarms): Class II (21 CFR 870.2300

External Transcutaneous Cardiac Pacemakers (Non-invasive): Class II (21CFR 870.5550)

Oximeters: Class II (21 CFR 870.2700)

Description:

The ZOLL R Series External Defibrillator is indicated for the defibrillation, Noninvasive Transcutaneous Pacing, multi-parameter monitoring of patient vital signs, including: ECG Monitoring, Pulse Oximetry, CPR performance and data printing and recording for resting patients in critical care and transport. The ZOLL R Series is intended for use by qualified medical personnel who are trained and authorized to respond to medical emergencies, to facilitate the ability to monitor and assess the physiological characteristics of the indicated patients in a critical care environment. The design facilitates table top use while still providing a light weight and easy to carry device for transport.

The device is capable of providing Basic Life-Saving (BLS) personnel the option of analyzing an adult or pediatric patient's ECG signal via the Advisory feature on the device. The Advisory Algorithm will determine if the acquired heart rhythm is shockable or non-shockable and will prompt the end-user to provide therapy in

the event of a shock advised determination. The user will be prompted to re-assess the patient in the event a no shock advised determination is returned.

Therapy is provided by using defibrillation electrode products specifically designed to be attached to the ZOLL R SERIES. When used in conjunction with ZOLL ***Ready***•pad***z*** One-step™ CPR or ***Ready***•pad***z*** One-step™ Complete Multifunction Electrodes the R SERIES provides CPR compression performance feedback to the user through displayed symbols, text messages and voice prompts.

Substantial Equivalence:

The features and functions of the ZOLL R SERIES are substantially equivalent to those of the ZOLL E SERIES Defibrillator: 510(k) No. k042007, cleared 4/07/2005, and the ZOLL AED Pro Defibrillator, 510(k) No. k041892, cleared 2/04/2005.

Intended Use:

Defibrillation

Use of the R Series products in the manual and semiautomatic modes for defibrillation is indicated on victims of cardiac arrest where there is apparent lack of circulation as indicated by:

- Unconsciousness
- Absence of breathing
- Absence of pulse.

This product should be used only by qualified medical personnel for converting ventricular fibrillation and rapid ventricular tachycardia to sinus rhythm or other cardiac rhythms capable of producing hemodynamically significant heartbeats.

In manual mode, the unit can also be used for synchronized cardioversion to terminate atrial fibrillation (AF) or ventricular tachycardia (VT) by using the R wave of the patient's ECG as a timing reference. A qualified physician must decide when synchronized cardioversion is appropriate.

The advisory function should be used to confirm ventricular fibrillation and wide complex ventricular tachycardia in patients meeting the three conditions indicating lack of circulation (previously listed).

External Pacemaker (Pacer Version Only)

This product may be used for temporary external, demand or non-demand pacing, as an alternative to endocardial stimulation. External cardiac pacing is indicated for use on conscious or unconscious patients in asystole, profound bradycardia or any other conditions determined by a clinician to require external pacing.

ECG Monitoring

The device is indicated for monitoring a patient's electrocardiogram (ECG), via the 3 or 5 lead patient cable, MFE Pads, or through the paddles, for the purposes of identifying and diagnosing cardiac rhythms and dysrhythmias and calculating heart rate.

CPR Monitoring

The CPR monitoring function provides visual and audio feedback designed to encourage rescuers to perform chest compressions at the AHA/ERC recommended rate of 100 compressions per minute. Voice and visual prompts encourage a compression depth of 1.5 to 2 inches (3.8 to 5.0 cm) for adult patients.

The CPR monitoring function is not intended for use on patients under 8 years of age.

SpO_2 Option *(if equipped)*

The SpO_2 Option with Masimo Set Technology is indicated for the continuous noninvasive monitoring of arterial oxygen saturation (SpO_2) and pulse rate for adult, pediatric and neonatal patients, during both no motion and patient motion conditions, and for patients who are well or poorly perfusing in the hospital or pre-hospital environments.

Comparison of Technological Characteristics

The ZOLL R Series design characteristics are fundamentally the same scientific technologies as those of the indicated predicate devices; the technology is very similar to that of the ZOLL E Series. The ZOLL R Series provides monitoring of patient vital signs, including: ECG Monitoring and Pulse Oximetry, using technology very similar to that of the predicate ZOLL E Series.

The ZOLL R Series advises users to deliver a shock, perform CPR or conduct patient assessment through audible and visual prompts nearly identical to those used by the indicated predicate devices. The ZOLL R Series acquires and analyzes ECG signals and provides shock advisory determinations for adult and pediatric patients, utilizing the identical ECG Analysis Algorithms that are incorporated into the predicate ZOLL AED Pro Defibrillator. ZOLL's proprietary CPR Aid feature provides users with performance feedback for compression depth and rate similar to the ZOLL AED Pro.

Performance Testing:

Extensive performance and software testing ensures that the ZOLL R Series Defibrillator meets all of its functional requirements and performance specifications. Safety testing assures the device complies with applicable sections of recognized industry and safety standards.

Conclusion

Performance and safety testing of the ZOLL R Series Defibrillator demonstrates that its features, functions and incorporated interpretive algorithm are substantially equivalent to that of the indicated commercially distributed predicate devices with regard to performance, safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 17 2006

ZOLL Medical Corporation
c/o Mr. Sean Reynolds
Regulatory Affairs Engineer
Worldwide Headquarters
269 Mill Road
Chelmsford, MA 01824-4105

Re: K060559
TradeDevice Name: Zoll R Series Defibrillator
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillators
Regulatory Class: Class III (three)
Product Code: MKJ, LDD, DRO, DQA, LIX
Dated: August 10, 2006
Received: August 14, 2006

Dear Mr. Reynolds:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

FOR Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 – INDICATIONS FOR USE

510(k) Number (if known): K060559

Device Name: ZOLL R Series

Defibrillator Function

Intended Use — Manual Operation

Use of the R Series products in the manual mode for defibrillation is indicated on victims of cardiac arrest where there is apparent lack of circulation as indicated by:

- Unconsciousness
- Absence of breathing
- Absence of pulse.

This product should be used only by qualified medical personnel for converting ventricular fibrillation and rapid ventricular tachycardia to sinus rhythm or other cardiac rhythms capable of producing hemodynamically significant heart beats.

In manual mode, the unit can also be used for synchronized cardioversion of certain atrial or ventricular arrhythmias. A qualified physician must decide when synchronized cardioversion is appropriate.

The advisory function should be used to confirm ventricular fibrillation and wide complex ventricular tachycardia (greater than 150 beats per minute) in patients meeting the three conditions indicating lack of circulation (listed above).

Intended Use — Semiautomatic Operation (AED)

The R Series products are designed for use by emergency care personnel who have completed training and certification requirements applicable to the use of a defibrillator where the device operator controls delivery of shocks to the patient.

They are specifically designed for use in early defibrillation programs where the delivery of a defibrillator shock during resuscitation involving CPR, transportation, and definitive care are incorporated into a medically approved patient care protocol.

Use of the R Series in the Semiautomatic mode for defibrillation is indicated on victims of cardiac arrest where there is apparent lack of circulation as indicated by:

- Unconsciousness
- Absence of breathing
- Absence of pulse.

(continued on next page)

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K060559

Indications for Use
(continued from previous page)

Specifications for the ECG rhythm analysis function are provided in the section, "ECG Rhythm Analysis Algoirhtm Accuracey" on page A-26.

When the patient is less than 8 years of age or weighs less than 55 lbs. (25 Kg), you must use ZOLL pediatric defibrillation electrodes. Do not delay therapy to determine the patient's exact age or weight.

Intended-Use – ECG Monitoring

The unit is intended for use when ECG monitoring is indicated to evaluate the patient's heart rate or ECG morphology. In ECG monitoring mode, the unit is intended to be used by personnel who are qualified by training in the use of the R Series defibrillator, basic life and/or advanced life support, or other physician-authorized emergency medical training.

Intended-Use – CPR Monitoring

The CPR monitoring function provides visual and audio feedback designed to encourage rescuers to perform chest compressions at the AHA/ERC recommended rate of 100 compressions per minute. Voice and visual prompts encourage a compression depth of 1.5 to 2 inches (3.8 to 5.0 cm) for adult patients.

The CPR monitoring function is not intended for use on patients under 8 years of age.

External Pacemaker (Pacer Version Only)

Intended Use — Pacemaker

This product can be used for temporary external cardiac pacing in conscious or unconscious patients as an alternative to endocardial stimulation.

The purposes of pacing include:

Resuscitation from standstill or bradycardia of any etiology:

Noninvasive pacing has been used for resuscitation from cardiac standstill, reflex vagal standstill, drug induced standstill (due to procainamide, quinidine, digitalis, b- blockers, verapamil, etc.) and unexpected circulatory arrest (due to anesthesia, surgery, angiography, and other therapeutic or diagnostic procedures). It has also been used for temporary acceleration of bradycardia in Stokes-Adams disease and sick-sinus syndrome. It is safer, more reliable, and more rapidly applied in an emergency than endocardial or other temporary electrodes.

As a standby when standstill or bradycardia might be expected:

Noninvasive pacing may be useful as a standby when cardiac arrest or symptomatic bradycardia might be expected due to acute myocardial infarction, drug toxicity, anesthesia or surgery. It is also useful as a temporary treatment in patients awaiting pacemaker implants or the introduction of transvenous therapy. In standby pacing applications, noninvasive pacing may provide an alternative to transvenous therapy that avoids the risks of displacement, infection, hemorrhage, embolization, perforation, phlebitis and mechanical or electrical stimulation of ventricular tachycardia or fibrillation associated with endocardial pacing.

Suppression of tachycardia:

Increased heart rates in response to external pacing often suppress ventricular ectopic activity and may prevent tachycardia.

(continued on next page)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K060559

Indications for Use
(continued from previous page)

Pediatric Pacing

Pacing can be performed on pediatric patients weighing 33lb. (15kg) or less using ZOLL pediatric hands-free therapy electrode pads. Prolonged pacing (in excess of 30 minutes), particularly in neonates, could cause burns. Periodic inspection of the underlying skin is recommended.

Intended-Use – SpO_2 Monitoring

The R Series pulse oximeter, with the Masimo® SET® technology and the LNOP® series of oximeter sensors, is indicated for the continuous, noninvasive monitoring of arterial oxygen saturation (SpO_2) and pulse rate during both no-motion and patient motion conditions for adult patients, and no motion conditions for pediatric and neonatal patients in a hospital or prehospital environment.

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K060559